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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,060	02/14/2002	Tatiana Segura	1720-1-003N	8493

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EXAMINER

KETTER, JAMES S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/076,060

Applicant(s)

SEGURA ET AL.

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-11, 13-21, 23 and 25-29 is/are rejected.
- 7) ☒ Claim(s) 5, 6, 12, 22 and 24 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10 September 2002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the

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required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claims 5, 6, 12, 22 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 11, 13-17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Zheng et al. (AL, of record).

(Zheng et al. is listed as having a Web release date of 15 February 2000, according to the Abstract listed at the internet web site of the journal.)

Zheng et al. Teaches, e.g., as summarized in the abstract, the attachment of DNA to a polymer surface using polyethyleneimine (PEI), which PEI is covalently attached to the surface. PEI is a polycationic polymer, which Zheng et al. teaches is known to be used for delivering DNA to cells, at p. 254, at the paragraph bridging the columns. It is also taught there that the amino groups on PEI are used for covalent attachment. The polymers taught in Zheng et al. include PCBZL, which is a derivatized polylysine, hence a peptide or a peptoid polymer. See page 255, left-hand column. With respect to claims 15 and 20, the control of the transfection process using the complex through surface density, location and number of bonds is inherent to the process taught by Zheng et al., even if no conscious control was being employed, in that these three factors contribute to determining the efficiency (or rate) of transfection, and in that sense “control” it. (Note, for comparison, that the phase in which water is present in a system, i.e., ice, liquid or steam, is “controlled” by factors such as temperature, pressure and solute concentrations.) With respect to claim 17, at page 255 it is taught that an 18 mm coverslip was used to create the polymer sheet. This represents about 2.5 cm^2 . With 1 to 10 micrograms of DNA being attached thereto, as shown in Figure 1B, 0.25 to $2.5 \text{ micrograms/cm}^2$ of DNA results. With respect to claim 19, the internalization of released complex is inherent to the method of Zheng et al., in that such is the widely accepted mechanism for lipid-mediated transfection known in the art. There is no reason to suppose that the mechanism in the method of Sabatini

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differs from that known conventionally. Indeed, at page 257, left-hand column, first full paragraph, Zheng et al. notes that the data support an internalization mechanism as being most likely.

Claims 1-3, 7-11, 13-21 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Sabatini (A, newly cited).

Sabatini teaches, e.g., as summarized in Figure 1, a method of transfecting cells comprising combining DNA (cloned cDNA) with a lipid transfection reagent (as well as a protein), followed by spotting the mixture on a glass slide where it is allowed to dry, followed by contact with the cells which permits transfection to occur. With respect to claims 2, 3, 7-10, 13, 16, 18, 21 and 23, Sabatini teaches at, e.g., column 3, lines 31-49, that the lipid-DNA mixture becomes affixed to the substrate (glass slide) upon drying, and at the paragraph bridging columns 9 and 10, that the lipid may be a lipofection mixture made from one or more of Effectene™, Eugene™ or Lipofectamine™. These are cationic lipids which coat the nucleic acid of interest, and as such, inherently must be the portion of the DNA-lipid complex which contacts the substrate. While it is not specified what functional group of any or each of the lipids contacts the substrate, clearly there must be at least one such group in each complex, or there would not be any contact with the complex and the substrate. There is neither any teaching nor scientific reasoning that the interaction of said complexes is covalent, which leaves non-covalent as the mode by which the complexes adhere to the substrate. The interaction inherently must be reversible to the extent that that DNA finds its way into the target cells. With respect to claims 15 and 20, the control of the transfection process using the complex through surface density,

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location and number of bonds is inherent to the process taught by Sabatini, even if no conscious control was being employed, in that these three factors contribute to determining the efficiency (or rate) of transfection, and in that sense “control” it. (Note, for comparison, that the phase in which water is present in a system, i.e., ice, liquid or steam, is “controlled” by factors such as temperature, pressure and solute concentrations.) With respect to claim 17, the teachings of Sabatini at column 8, lines 22-25, of spots of 100 microns diameter, in combination with the teachings of 10-50 picograms DNA per spot at Figure 4D, yields a density of DNA on the substrate of about 0.1-0.5 micrograms per cm^2 . With respect to claim 19, the internalization of released complex is inherent to the method of Sabatini, in that such is the widely accepted mechanism for lipid-mediated transfection known in the art. There is no reason to suppose that the mechanism in the method of Sabatini differs from that known conventionally.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10 and 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8-10 recite the terms “modified polylinker” and “non-modified polylinker”.

However, the status of a compound as “modified” is relative to a starting compound. However, one of skill cannot simply look at a compound structure and know if it has been “modified” from

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some other compound. The definition presented in the specification does not make clear the meanings of these two terms. As such, the metes and bounds of the instant claims are indefinite.

Claims 25-29 recite the term "specifically bound". However, "specific" binding is a matter of binding affinity, and thus a matter of degree, which is not specified or defined in either the instant specification or the prior art. As such, the metes and bounds of the instant claims are not defined.

Certain papers related to this application, OTHER THAN OFFICIAL RESPONSES, may be submitted directly to the Examiner by facsimile transmission at (571) 273-0770. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). (703) 872-9306 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter fax number unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.


Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
March 4, 2004



**JAMES KETTER
PRIMARY EXAMINER**